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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/894,788	08/27/97	GIACOMONI	05/25.0213

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EXAMINER
CHANNAVAJJALA, L

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 07/21/98

Please find below and/or attached an Office communication concerning this application or  
proceeding.

Commissioner of Patents and Trademarks

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# Office Action Summary

Application No.  
**08/894,788**

Applicant(s)  
**Paolo Giacomoni**

Examiner  
**Lakshmi Channavajjala**

Group Art Unit  
**1615**



☒ Responsive to communication(s) filed on May 4, 1998

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 31-38, 40-54, and 56-66 is/are pending in the applicat

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 31-38, 40-54, and 56-66 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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Receipt of amendment B and the attachments dated 5-4-98 is acknowledged.

***Response to Arguments***

1. Applicant's arguments filed on 5-4-98 have been fully considered but they are not persuasive. The reasons are as follows:

Rejection of claims 31-34, 43-45 and 59-61 under 35 U.S.C. 103 (a) as unpatentable over Teale in view of Williamson

The applicants argue that the references used by the examiner fails to teach or suggest a composition comprising an NO synthase inhibitor in combination with a component capable of causing cutaneous irritation and therefore there is lack of motivation in combining the teachings and rejecting the claims as was done in the previous Office Action.

However, The claims in the instant invention (claims 31-47) are directed towards a composition containing a cosmetic or pharmaceutical and not to the cutaneous irritant effect. The reference of Teale teaches antiinflammatory agents, which are used as pharmaceutical agents and saline as a pharmaceutically acceptable medium. Thus the reference teaches all the ingredients which are within the scope of the above claims i.e., "atleast one cosmetic or pharmaceutical product, a pharmaceutically acceptable medium and No synthase inhibitors" (claim 31).

Williamson recognizes several physical, chemical and biological agents capable of causing inflammation of skin which obviously irritates the skin. Therefore, the motivation to combine the teachings of Wiiliamson with that of Teale flows logically.

Rejection of claims 35 and 51 under 35 U.S.C. 103 (a) as unpatentable over Teale in view of Wilhelm and Williamson

The applicant requested a clarification on page 6 of the response to the previous Office Action. The reference of Wilhelm teaches surfactants induce skin irritation representing a clinical

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situation of contact dermatitis. Williamson recognizes contact dermatitis as an inflammatory reaction which involves NO formation and the reaction inhibited by NO synthase inhibitors. Thus one can conclude from the teachings of Wilhelm and Williamson (not Williamson alone) that surfactants may lead to contact dermatitis by way of the producing nitric oxide. Therefore, it would have been obvious for one of an ordinary skill in the art to combine the teachings of Teale, Williamson and Wilhelm to inhibit the cutaneous irritation caused by surfactants by inhibiting NO synthase.

Rejection of claims 36-39, 47, 52-55, 63 and 64 under 35 U.S.C. 103 (a) as unpatentable over Yu in view of Williamson

Similarly, the low pH due to alpha hydroxy acids and ketoacids cause inflammation including inflammatory dermatoses (see abstract of Yu) and it would have been obvious for a skilled artisan to identify for the various compounds capable of causing cutaneous irritation, including those taught by Yu.. Although the teachings of Williamson are directed to “prevention/treatment of diseases linked to nitric oxide production by leukocytes and other non hemopoietic cells”, Williamson recognizes several physical, chemicals such as toxins and caustic substances and biological agents capable of causing inflammation including skin conditions such as dermatitis. It is further obvious from the teachings of Yu that the burning of skin due to low pH of ketoacids and alpha hydroxy acids is a caustic reaction. Therefore the motivation to combine the teachings of Teale, Wilhelm and Williamson flows logically. Further, the burden is shifted to the applicant to show that the anti-inflammatory agents in the above references do not cause skin irritation.

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Rejection of claims 45, 46, 61 and 62 under 35 U.S.C. 103 (a) as unpatentable over Teale in view of Ahluwalia

Ahluwalia teaches application of NO synthase inhibitor to the skin. The reference has been cited to show that the NO synthase inhibitors (not disclosed by Teale) claimed in the instant invention are known in the art, and that these inhibitors can be applied topically. It would have been obvious for one of an ordinary skill in the art to use any NO synthase inhibitor in the teachings of Teale with the expectation of successfully inhibiting nitric oxide production.

Further, the teachings of Teale suggest that the NO synthase inhibitors can be administered by various routes i.e., subcutaneous or by infusion. A subcutaneous route of administration implies application through the skin. Infusion is a generic teaching for mucosal administration.

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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### *Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is (703) 308-2438. The examiner can normally be reached Monday through Friday from 8:00am to 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax number for this Group is (703) 305-5408.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. § 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

**All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of confidentiality requirements of U.S.C. § 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.**

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703-305-<sup>1235</sup>2351)



Lakshmi S. Channavajjala

07/10/98



THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
ART UNIT 152-1615